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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,147	10/29/2003	Jian Zhang	18136-1050 C1	1191

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,147	ZHANG ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-15, 25-27, drawn to polynucleotides, vectors, host cells and methods of producing a polypeptide, classified in class 435, subclass 69.1.

II. Claims 9, 22, 23, drawn to antisense nucleic acids, classified in class 536, subclass 24.5.

III. Claims 16-18, drawn to polypeptides, classified in class 530, subclass 350.

IV. Claims 19, 20, drawn to methods of identifying agonists and antagonists, classified in class 435 , subclass 7.21.

V. Claim 21, drawn to antibodies, classified in class 530, subclass 350.

VI. Claim 24, drawn to transgenic animals, classified in class 800, subclass 3.

VII. Claims 28-33, drawn to agonists and antagonists of a VNO receptor, classification dependent on the chemical identity of the agonist. or antagonist.

VIII. Claims 34-37, drawn to methods of identifying a polynucleotide, classified in class 435, subclass 6.

IX. Claims 38-42, drawn to methods of gene therapy, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions

for the following reasons: Groups I-III and V-VII are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group III can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group III, such as a probe in nucleic acid hybridization assays. The protein of Group III can be used in materially different methods other than to make the antibody of Group V, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group V can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods. Although, the protein Group III can be used to identify the agonist or the antagonist of Group VII, the protein could also be used to produce the antibody of Group V. Although, the DNA of Group I can be used to produce the protein of Group I which can be used to identify the agonist or the antagonist of Group VII, the DNA could also be used to as a diagnostic probe. The agonist and the antagonist of Group VII are distinct from the protein and from the DNA because the agonist and antagonist could be obtained from sources other than those employing the protein of Group III or the DNA of Group I, such as from commercial vendors. Furthermore, the antibody of Group V is distinct from the antagonist and the agonist of Group VII, because an antibody which binds to a protein does not necessarily alter the activity of the protein as required of an antagonist or agonist.

The antisense nucleic acid of Group II is unrelated to the products of either Groups I, III, V-VII. Similarly, Although the DNA of Group I can be used to make the transgenic animal of Group IV,

the DNA can be used in other materially and functionally distinct methods, such as in gene therapy or as a probe in nucleic acid hybridization assays. The products of Groups I-III, V, and VII are not required to make the transgenic animal of Group VI.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV, VIII and IX are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group IV requires a ligand binding assay, which is not required by any of the other groups. Group VIII requires methods of identifying alternate alleles of a gene, which is not required by any of the other groups. Group IX requires methods of gene therapy, which is not required by any of the other groups.

The polynucleotides of Group I are related to the methods of Groups IV, VIII and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups IV, VIII and IX because the polynucleotides of Group I can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, VIII and IX are materially and functionally distinct from the others.

The antisense polynucleotides of Group II are related to the methods of Groups IV and IX as product and process of use. In the instant case the polynucleotides of Group I are

patentably distinct from each of the methods of Groups IV and IX because the polynucleotides of Group II can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV and IX are materially and functionally distinct from the others. Furthermore, the antisense polynucleotides of Group ii and the methods of Group IV are patentably distinct because one is not required for the use of the other.

The polypeptides of Group III are related to the methods of Group IV as product and process of use. In the instant case the polypeptides of Group III are patentably distinct from each of the methods of Group IV because the polypeptides of Group III can be used in ways that are materially and functionally different than each of the methods because such as to make the antibodies of Group V. Furthermore, the polypeptides of Group III and the methods of Groups VIII and IX are patentably distinct because one is not required for the use of the other.

The antibodies of Group V are related to the methods of Group IV as product and process of use. In the instant case the antibodies of Group V are patentably distinct from each of the methods of Group IV because the antibodies of Group VI can be used in ways that are materially and functionally different than each of the such as to obtain the DNA of Group I Furthermore, the antibodies of Group V and the method of Groups VIII and IX are patentably distinct because one is not required for the use of the other.

The transgenic animals of Group VI and the methods of Groups IV, VIII, and IX are patentably distinct because one is not required for the use of the other.

The agonist and antagonist of Group VII and the methods of Group IV are related as product and process of use, and are patentably distinct because the agonist and antagonist of

Group VII can be used in ways that are materially and functionally different than the methods of Groups IV, such as in diagnostic methods that require labeling of the polypeptide or in therapeutic methods. Furthermore, the agonist and antagonist of Group VII and the methods of Groups XIII and IX are patentably distinct because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Claims 1-33 are generic to a plurality of disclosed patentably distinct species comprising a polypeptide of either SEQ ID NO: 3, 4, or 6, or a polynucleotide of either SEQ ID NO: 1, 2, 5, or 7. Claims 34-41 are generic to a plurality of disclosed patentably distinct species comprising the use (or relating to the potential use) of a polynucleotide of either SEQ ID NO: 1, 2, 7, or 8 or a polynucleotide encoding SEQ ID NO: 3, 4, or 6. Each SEQ ID NO represents a structurally and functionally distinct molecule, the use of one not being required for the use of any other. Further, although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO; and to search all species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, such species being appropriate to the Group chosen, e.g. if Group I is chosen then an appropriate species would be SEQ ID NO: 1, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649. Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

July 11, 2006

Brenda Brumback
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